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To: Commissioner of Patents and Trademarks
Washington, D.C. 20231

Response to Examiner's Action mailed 09/12/94

Serial Number : 08/031,562

Examiner: Julie Krsek-Staples, Ph.D.

Supervisory Patent Examiner: Christine M. Nucker

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This is in response to the Examiner's action of the above date.

Under the Examiner's "Response to Applicant's Arguments", page 5:

The Examiner acknowledges that anti-Recognin antibodies are cytotoxic to cancer cells, and notes that the presence of these antibodies is quantitatively associated with greater survival in human cancer patients; then the Examiner states:

"The statistical significance of the survival studies (in humans) shows that there is a correlation between anti-recognin antibodies and survival. However, it is not clear whether the antibodies themselves are capable of treating or preventing cancer or whether other factors are involved." (addition in parentheses is the Applicant's). The Examiner correctly cites for example tumor mass and tumor-host relationship as

no certificate

relevant 'other factors'.

In response, the applicant agrees that of course other factors are involved in cancer prevention and treatment. But it is not claimed by the applicant that Recognin vaccines are sufficient to overcome all other variables or factors in cancer prevention or treatment, any more than any prevention or treatment in medicine is ever properly so-claimed.

However, it is very relevant that actual survival in human cancer patients, the end-measure of the pressure of all 'other factors', is quantitatively related to the concentration of anti-Recognin antibody. This fact cannot be cited, to the applicant's knowledge, by any other currently available vaccine or antibody treatment. (Neither Cantrell's nor Rapp's issued patents, which are cited by the Examiner against the apllicant's application, provide human data of such end-measure effectiveness of the so-called vaccines which they have used in animals only.)

For another example of the involvement of other factors, on page 85 of the reference supplied by and used by the Examiner (Freda K. Stevenson, Int. J Clin Lab Res 22:84-89,1992), Stevenson points out the problems in using all tumor-associated antigens (TAAs) (other than the Recognins) as potential vaccines as follows:

"The TAAs are products of some normal cells and are often differentiation antigens; ----for passive antibody, --it is often acceptable to destroy some normal cells together with the target tumor cells---However, in an active immune response, such attack would be continuous and theoretically could lead to autoimmunity."

In the case of the Recognins, this particular 'other factor' is not a problem, since